

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TWINSTRAND BIOSCIENCES, INC., &
UNIVERSITY OF WASHINGTON,

Plaintiffs and Counterclaim
Defendants,

v.

GUARDANT HEALTH, INC.,

Defendant and Counterclaim
Plaintiff.

REDACTED - PUBLIC VERSION
(Filed December 4, 2023)
C. A. No. 21-1126-GBW-SRF

[REDACTED]

ORDER

Having reviewed the proposed joint pretrial order (D.I. 460) submitted by Plaintiffs TwinStrand Biosciences, Inc. and the University of Washington (collectively, “Plaintiffs”) and Defendant Guardant Health, Inc. (“Guardant”) regarding the jury trial scheduled to begin on November 6, 2023, **IT IS HEREBY ORDERED** that:

1. With respect to Plaintiffs’ motion *in limine* number 1, Plaintiffs request that the Court preclude Guardant from arguing that the ’127 patent is invalid for obviousness, based on IPR estoppel. D.I. 460, Ex. 15 at 4. Plaintiffs’ motion *in limine* number 1 is **GRANTED**. 35 U.S.C. § 315(e)(2) estops parties who initiate *inter partes* review that results in a final written decision from asserting in district court that a “claim is invalid on any ground that the petitioner raised or reasonably could have raised during that *inter partes* review.” *Cal. Inst. Of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 989 (Fed Cir. 2022). Guardant filed two petitions for IPR against the ’127 patent: the ’817 petition and the ’816 petition. *See Guardant Health, Inc. v. Univ. of Wash.*, IPR2022-00816 (P.T.A.B. Apr. 8, 2022), Paper

3; *Guardant Health, Inc. v. Univ. of Wash.*, IPR2022-00817 (P.T.A.B. Apr. 8, 2022), Paper 3. The board declined to institute the '816 petition but instituted the '817 petition. IPR2022-00816 (P.T.A.B. Oct. 12, 2022), Paper 16; IPR2022-00817 (P.T.A.B. Oct. 13, 2022), Paper 14. The PTAB issued a final written decision in the '817 IPR finding that no challenged claims were unpatentable. IPR2022-00817 (P.T.A.B. Oct. 10, 2023), Paper 47. Thus, the question before the Court is whether the grounds raised in the rejected '816 petition could “reasonably have been asserted” in the '817 petition. Guardant contends that those grounds could not have been asserted because the references were included in a denied petition. D.I. 460, Ex. 15, at 15. This argument is foreclosed by Federal Circuit precedent. *Intuitive Surgical, Inc. v. Ethicon LLC*, 25 F.4th 1035 (Fed. Cir. 2022). In *Intuitive*, the plaintiff filed three IPR petitions against a patent. *Id.* at 1038. While the third was pending, the Board issued final written decisions in the first two IPRs upholding the claims. *Id.* at 1039. The PTAB held that the plaintiff, Intuitive, was estopped from maintaining its challenges in the third IPR. *Id.* The Federal Circuit affirmed, holding that “Intuitive actually knew” of the art asserted in the third IPR when it filed the other petitions, and “could have made its challenges more pointed and specific so as to fit all of its grounds in two petitions satisfying the word limits.” *Id.* Similarly, Guardant “actually knew” of the prior art in the '816 petition when it filed the '817 petition. Accordingly, Guardant is estopped from arguing invalidity based on either set of prior art.

Guardant argues that *Shaw Indus. Grp., Inc. v. Automated Creel Sys., Inc.* controls. 817 F.3d 1293 (Fed. Cir. 2016). *Shaw* held that estoppel does not apply when a petitioner raises a ground in a petition, and the PTO denies institution on those grounds, because the petitioner could not reasonably have raised those grounds during the IPR proceedings. *Id.*

at 1300. However, *Shaw* has been explicitly overruled. See *Click-to-Call Techs. LP v. Ingenio, Inc.*, 45 F.4th 1363, 1370 (Fed. Cir. 2022) (“We recently overruled *Shaw*. In *Caltech*, we relied on *SAS*’s abrogation of the Board’s practice of partial institutions as undermining *Shaw*’s rationale”). Guardant incorrectly characterizes *Click-to-Call* as a subsequent Federal Circuit case that “continued to cite the reasoning of *Shaw*.” D.I. 460, Ex. 15 at 15; see *id.*

Guardant argues that *Intuitive* interpreted § 315(e)(1) (estoppel before the PTO), rather than § 315(e)(2) (estoppel before district courts). *Id.* While true, the language in the statutes is identical, so the Court finds that *Intuitive*’s logic applies to IPR estoppel before district courts as well as the PTO. Guardant also argues that *Intuitive* is not on point because it did not address the situation where one petition was denied. In that situation, the petitioner would be foreclosed from asserting any grounds in the denied petition in any other petition. *Id.* at 15-16. However, at the time of the filing of the (instituted) ’817 IPR, Guardant could have included any of the grounds from the ’816 IPR in the ’817 IPR. This is the precise holding of *Intuitive*, applying the plain language of § 315. See also *California Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 991 (Fed. Cir. 2022) (overruling *Shaw* and holding that “estoppel applies not just to claims and grounds asserted in the petition” because “[i]n a regime in which the Board must institute on all challenged claims and the petition defines the IPR litigation, this interpretation is the only plausible reading of ‘reasonably could have been raised’”). Accordingly, the Court finds that IPR estoppel applies, and grants Plaintiffs’ motion precluding Guardant from raising invalidity theories based on art asserted in the ’816 IPR.

2. With respect to Plaintiffs' motion *in limine* number 2, Plaintiffs request that the Court exclude evidence or argument that two of Guardant's prior art references, U.S. Patent No. 11,441,180 ("Bielas") and WO 2012/142213 ("Vogelstein"), are entitled to effective dates earlier than their publication dates. D.I. 460, Ex. 15 at 24. Plaintiffs' motion *in limine* number 2 is **DENIED**. The publication dates of both Bielas and Vogelstein post-date the '631 patent's priority date, but both claim priority to earlier-filed applications. There is no "presumption that a patent is entitled to the benefit of the filing date of its provisional precursor." *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1275, 1380 (Fed. Cir. 2015). Instead, the burden of production that a reference is invalidating, and the ultimate burden of persuasion, rests on Guardant. *Id.* at 1379. The patentee has "the burden of going forward with evidence either that the prior art does not actually anticipate, or . . . that it is not prior art because the asserted claim is entitled to the benefit of a filing date prior to the alleged prior art." *Id.* Only after such a showing has been made does the "burden of going forward again shift[] to the proponent of the invalidity defense, [Guardant], to convince the court that [the patentee] is not entitled to the benefit of the earlier filing date." *Id.*

Guardant has met its initial burden of production with respect to Bielas by asserting that Bielas was invalidating prior art. D.I. 460, Ex. 15 at 25. Thus, the burden shifted to Plaintiffs to show that Bielas is not prior art, or that the asserted claims are entitled to a filing date predating Bielas. Plaintiffs' expert argued that [REDACTED]. D.I. 460, Ex. 15 at 132-33. However, he stated that he had "not done any analysis to determine one way or the other whether Bielas is entitled" to claim priority to its provisional

application filing date. D.I. 460, Ex. 15 at 161 (Dr. Metzker Deposition at 23:8-24:10). Thus, the burden never shifted back to Guardant on the issue of whether Bielas was entitled to the priority date of its provisional application. The same applies to Vogelstein: Dr. Metzker never challenged the written description support for Vogelstein in its provisional. D.I. 460, Ex. 15 at 134-35. Accordingly, Guardant was not required to provide further evidence bolstering the publication date of Bielas and Vogelstein. *See Dynamic Drinkware*, 800 F.3d at 1379-1380. Therefore, Plaintiffs' motion *in limine* number 2 is denied.

3. With respect to Plaintiffs' motion *in limine* number 3, Plaintiffs request that the Court preclude Guardant from presenting evidence related to alleged claim copying. D.I. 460, Ex. 15 at 175. Originally, Plaintiffs asserted four patents: the '631, '127, '699, and '951 patents. Guardant alleged that claims of the '699 and '951 patents were copied from Guardant's patents. *Id.* at 176. Both of the patents that Guardant alleged were copied have been dismissed from the suit. D.I. 450. Thus, Plaintiffs seek to exclude all evidence of claim copying, on the grounds that it is irrelevant to any pending claim.

Plaintiffs' motion *in limine* number 3 is **GRANTED WITH A CAVEAT**. Guardant has indicated that "it does not intend to offer evidence of claim copying at trial unless Plaintiffs offer evidence or argument at trial that renders claim copying evidence relevant." D.I. 460, Ex. 15, at 195. The claim copying allegations could become relevant, if, for example, Plaintiffs impugn Guardant's intellectual property strategy. *See* D.I. 460, Ex. 15, at 196. However, the Court is not convinced at this time that the evidence of claim copying would be relevant if Plaintiffs "tout their patent portfolio beyond the two patents currently at issue" or "introduce testimony regarding their patent prosecution practices or

activities.” *Id.* at 196. Accordingly, the Court will require Guardant to request leave to raise evidence of claim copying if it believes that Plaintiffs have opened the door and such evidence has become relevant. *See Sonos, Inc. v. D&M Holdings, Inc.*, C.A. No. 14-1330-WCB, 2017 U.S. Dist. LEXIS 193078, at *3 (D. Del. Nov. 21, 2017) (excluding evidence until the other party opens the door).

4. With respect to Guardant’s motion *in limine* number 1, Guardant requests that the Court preclude evidence and argument relating to lawsuits between Guardant and Illumina, Foundation Medicine, Inc. (“FMI”), and Personal Genome Diagnostics, Inc. (“PGDx.”). D.I. 460, Ex. 16 pt. 1, at 4. Guardant’s motion *in limine* number 1 is **GRANTED**. The cases between Guardant and these parties were over different patents that are not at issue in this suit. *Id.* at 6. Guardant has agreed that the parties’ experts should be permitted to testify as to any facts or opinions addressed in their expert reports regarding the agreements resolving the prior litigation. *Id.* The Court agrees that, outside of that limited purpose (and the evidence required for the jury to understand the context of the prior litigation agreements), evidence from another trial on different patents is irrelevant and likely to cause jury confusion and prejudice. *See* Fed. R. Evid. 403. Plaintiffs have stated that they “do not intend to present evidence regarding *Illumina* unless Guardant opens the door,” and that Plaintiffs “do not intend to present any allegations from *FMI* or *PGDx* to the jury.” D.I. 460, Ex. 16 pt. 2, at 42. Plaintiffs argue only that they should be able to present factual evidence underlying those trials. *Id.* Even when courts exclude evidence of the “existence of ... other litigation”, or the arguments therein, “evidence that has been developed in an IPR or other litigation—including testimonial as well as documentary evidence—may be used at trial.” *Siemens Mobility Inc. v. Westinghouse Air Brake Techs. Corp.*, No. CV 16-

284-LPS, 2019 WL 77046, at *2 (D. Del. 2019). But, Plaintiffs have yet to identify any disputed issue in this case for which the underlying evidence is relevant and not hearsay. Given the possible prejudice that might arise from introducing the underlying allegations of the other suits (e.g. claim copying, spoliation, and inequitable conduct), the Court deems it appropriate to require Plaintiffs to seek permission at sidebar before introducing evidence from other trials. Accordingly, the Court grants Guardant's motion.

5. With respect to Guardant's motion *in limine* number 2, Guardant requests that the Court preclude Plaintiffs from presenting evidence and argument regarding ownership of Guardant's technology and patents, including evidence regarding alleged copying by Guardant. D.I. 460, Ex. 16B at 1. Guardant's motion is **GRANTED-IN-PART** and **DENIED-IN-PART**. After Plaintiffs filed this suit against Guardant in August 2021 asserting infringement of four patents, Guardant filed counterclaims asserting four of its own patents in January 2022. D.I. 30. On September 22, 2022, Guardant dismissed those counterclaims with prejudice. D.I. 441. Thus, the inventorship and ownership of Guardant's patents are no longer at issue. Accordingly, Plaintiffs may not argue at trial that Guardant did not conceive of, or reduce to practice, its patents, nor may Plaintiff's argue that Guardant lacks ownership of its patents, as such evidence makes no disputed fact more or less likely. *See* Fed. R. Evid. 401, 402. However, Plaintiffs state they intend to introduce evidence that Guardant copied Plaintiffs' technology as evidence of infringement, non-obviousness, and willfulness. D.I. 460, Ex. 16B (Plaintiffs' Response) at 1. Evidence that Guardant allegedly copied Plaintiffs' technology is relevant for Plaintiffs' stated purposes. *See Adv. Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1287 (Fed. Cir. 2000) ("evidence of copying ... supports a claim of infringement under the

doctrine of equivalents”); *Liqwd, Inc. v. L'Oreal, USA, Inc.*, 941 F.3d 1133, 1136 (Fed. Cir. 2019) (explaining that copying is an “objective indicia of non-obviousness”); *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 183 (Fed. Cir. 1994). Thus, Plaintiffs may argue at trial that Guardant copied Plaintiffs’ patented technology for the purpose of establishing infringement, non-obviousness, and willfulness. *See id.* Guardant argues that Plaintiffs’ presentation of alleged copying is unfairly prejudicial due to a lack of nexus between any copying and a remaining claim. D.I. 460, Ex. 16B (Guardant’s Reply) at 1. However, the Court will not grant summary judgment on the issue of whether Plaintiffs can show a nexus between any alleged copying and a claim of infringement, non-obviousness and/or willfulness. *See Sonos, Inc. v. D&M Holdings Inc.*, 297 F. Supp. 3d 501, 521 (D. Del. 2017) (a jury “is fully competent to evaluate the evidence and draw its own conclusion about” copying without expert testimony). Guardant may renew its objection at trial if it believes Plaintiffs are offering evidence for an improper purpose.

6. With respect to Guardant’s motion *in limine* number 3, Guardant requests that the Court exclude evidence regarding [REDACTED]. D.I. 460, Ex. 16 pt. 2, at 192. Guardant’s motion *in limine* number 3 is **DENIED**. As an initial matter, the Court is not convinced that Rule 408 bars the evidence—[REDACTED]
[REDACTED]. D.I. 460, Ex. 16 pt 3, at 3 n. 3; *see Deere & Co. v. International Harvester Co.*, 710 F.2d 1551, 1557 (Fed.Cir.1983) (“Rule 408, on its face, is limited to actual disputes over existing claims and, accordingly, cannot be applicable to an offer, albeit one ultimately rejected, to license an, as yet, uncontested patent.”). Moving to Rule 403, Guardant has identified two forms of prejudice. D.I. 460, Ex. 16 pt. 2 at 194-95. First, Guardant identifies the risk that the jury may be confused about whether

infringement was possible pre-suit. *Id.* This risk is relatively small and can be resolved through jury instructions. Guardant also identifies the risk that the jury may believe that “defendants certainly would not have spent millions of dollars for a license if they did not believe the patent truly covered the accused technology.” *Id.* at 195 (quoting *St. Clair IP Consultants v. Toshiba Corp.*, No. 09-cv-354-KAJ, 2015 WL 5826815, at *4 (D. Del. Oct. 2, 2015)). The Court agrees there is at least some risk of prejudice. However, in *St. Clair*, the plaintiff was planning to introduce the [REDACTED] as evidence that the “patent must be valid and must cover [Defendant’s] technology,” and did not identify any permitted relevant purpose for the evidence. 2015 WL 5826815 at *4. The [REDACTED] implicated the asserted patent “only tangentially” and had only “dubious relevance.” *Id.* In contrast, there is significant legal relevance to [REDACTED]. Pre-issuance discussions are relevant to show that Guardant was aware of Plaintiffs’ technology, what the value would have been to Guardant at the time, and whether Guardant copied Plaintiffs’ technology (a secondary consideration of non-obviousness). *See Philippi-Hagenbuch, Inc. v. W. Tech. Servs. Int’l, Inc.*, 2013 WL 2419934, at *3 (C.D. Ill. June 3, 2013) (holding that knowledge of the existence of applications is relevant to willfulness, damages, and invalidity). This legal relevance is not substantially outweighed by the risk of unfair prejudice. Therefore, the Court will not preemptively exclude all evidence relating to [REDACTED]. *See* Fed. R. Evid. 403.

Date: November 1, 2023



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE